

REMARKS

Claims 1-9 were previously pending in this application. Claim 1 has been amended to reflect the elected subject matter, non-elected claims 3-9 have been cancelled without prejudice to or disclaimer of the underlying subject matter, and new claims 10-15 have been added. Support for the new and amended claims can be found throughout the specification, for example, at page 6, line 33 through page 7, line 15, page 18, line 25 through page 19, line 18, in the sequence listing and in the claims as originally filed. The specification has been amended at the request of the Examiner to remove hyperlinks and browser executable code. No new matter enters by way of these amendments.

1. Restriction/Election

Applicants acknowledge the finality of the restriction requirement but maintain their traversal. To facilitate prosecution, however, Applicants have removed the non-elected claims from the application.

Applicants further acknowledge the finality of the election requirement to a single nucleotide sequence, but maintain their traversal. Applicants submit that election of a single nucleotide sequence is improper and Applicants believe no serious burden would result by the search and examination of at least ten nucleotide sequences. The election of a single nucleic acid sequence contravenes the USPTO policy as set forth in the Manual of Patent Examining Procedure stating that “to further aid the biotechnology industry in protecting its intellectual property without creating an undue burden on the Office, the Commissioner has decided ... to permit a reasonable number of such nucleotide sequences to be claimed in a single application.” (M.P.E.P., 8th ed., rev. 1, February 2003, Section 803.04). The MPEP further provides that “[i]t

has been determined that normally ten sequences constitute a reasonable number for examination purposes.” (emphasis added) *Id.* While the Examiner requires that a single nucleotide sequence be selected, no reason has been provided for this deviation from articulated Patent Office policy.

Although Applicants disagree with the election requirement of a single nucleotide sequence, to facilitate prosecution the claims have been amended to reflect the elected SEQ ID NO: 4.

2. Specification – Browser Executable Code

The specification has been objected to for purportedly containing “embedded hyperlink and/or other form of browser-executable code.” Office Action at pages 2-3.

The purpose of the requirement that hyperlinks or other forms of browser executable code be removed from the specification is so that on the United States Patent and Trademark Office website, one cannot click on the hyperlink and be transported to another, potentially commercial, website. This requirement does not exclude the listing of a website that is not present as a hyperlink.

Applicants have amended the specification to remove the phrase “http://,” embedded hyperlinks and other forms of browser-executable code (instead listing the websites using the format “available on the worldwide web at ‘websitename.html’”). The citation of a website in this format does not offend United States Patent and Trademark Office policy, and should be allowed in an application.

In light of these amendments, applicants respectfully request withdrawal of the objection to the specification.

3. Claim Rejections – 35 U.S.C. § 101

Claims 1 and 2 were rejected under 35 U.S.C. § 101, because the claimed invention is allegedly “not supported by either a specific and substantial utility or a well-established utility.” Office Action at page 3. Applicants respectfully traverse this rejection.

The Examiner acknowledges that the specification describes multiple utilities for the present invention, including “to acquire genes ... acquire promoters or cis-regulatory elements, or to generally obtain nucleic acid molecules from other organisms.” Office Action at page 3. However, despite this admission and numerous additional uses cited throughout the specification, the Examiner contends that none of these utilities constitutes a “specific” or “substantial” utility. *Id.* at pages 3-4. In particular, the Examiner alleges that the disclosed utilities are “generally applicable to any nucleic acid and therefore are not particular to the nucleic acid sequence being claimed.” *Id.* at page 3. In addition, the Examiner contends that “further basic research would need to be conducted to characterize it.” *Id.* at page 4. Applicants respectfully disagree.

It is well-established law that “when a properly claimed invention meets at least one stated objective, utility under section 101 is clearly shown.” *Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 958, 220 U.S.P.Q. 592, 598 (Fed. Cir. 1983). As acknowledged by the Examiner, the specification describes multiple objectives and utilities that are met by the present invention. Moreover, the claimed nucleic acid molecules are useful in determining the presence or absence of polymorphisms, isolating specific promoter sequences and to obtain nucleic acid homologues, *etc.* See, *e.g.*, specification, beginning at page 33, under heading “Uses of the Agents of the Invention”.

Many of these uses are directly analogous to the use of a microscope. An important utility of a microscope resides in its use to identify and characterize the structure of biological tissues in a sample, cell or organism. Significantly, the utility of a microscope under 35 U.S.C. § 101 is not compromised by its use as a tool in this manner. Many of the presently disclosed utilities are directly analogous to the utilities of a microscope, *i.e.*, the claimed nucleic acid molecules may be used to identify and characterize nucleic acid molecules within a sample, cell, or organism. Such utility is indistinguishable from the legally sufficient utility of a microscope. Thus, the presently disclosed sequences possess the requisite utility under 35 U.S.C. § 101.

In the Office Action, the Examiner attempts to undermine the existing utilities by stating that they are “generally applicable to any nucleic acid,” Office Action at page 3, and “not particular to the nucleic acid sequences being claimed.” *Id.* In short, the Examiner suggests that the asserted utilities are legally insufficient simply because other molecules can be used for the same purpose. This position is wrong as a matter of law – there is no requirement of exclusive utility in the patent law. *See Carl Zeiss Stiftung v. Renshaw PLC*, 945 F.2d 1173, 1180, 20 U.S.P.Q.2d 1094, 1100 (Fed. Cir. 1991) (“An invention need not be the best or the only way to accomplish a certain result...”).

Such an argument implies that a new golf club has no legal utility because other golf clubs can be used for the same purpose, *i.e.*, hitting golf balls. Such a result is not only untenable, but requires reading “into the patent laws limitations and conditions which the legislature has not expressed,” a practice condemned by the Supreme Court. *See Diamond v. Chakrabarty*, 447 U.S. 303, 308, 206 U.S.P.Q. 193, 196 (1980), *quoting United States v. Dubilier Condenser Corp.*, 289 U.S. 178, 199, 17 U.S.P.Q. 154, 162 (1933). Thus, it must be the

case that a utility, generic to a broad class of molecules, does not compromise the specific utility of an individual member of that class.

Applicants note that the claimed nucleic acid molecules encompass many utilities. Some of these utilities may be common to a broader class of molecules. For instance, nucleic acid sequences may generally be used to identify and isolate related sequences. However, when used in this manner, the result is not generic. Rather, the claimed nucleic acid molecules will identify a *unique* subset of related sequences. This subset of related sequences is specific to the claimed sequence and cannot be identified by any generic nucleic acid molecule. For example, a random nucleic acid molecule would not provide this specific utility. Referring again to the golf club analogy, the club is still generically hitting a golf ball, but is uniquely designed to hit the ball in a manner that is distinct from other clubs. Once again, Applicants assert that the claimed nucleic acid molecules exhibit the requisite utility under 35 U.S.C. § 101.

Moreover, the specification also discloses the isolation of the claimed nucleic acid molecules from cDNA libraries prepared from partially to fully open flower tissue of rice. Specification at page 33, lines 4-14, page 84, line 15 through page 86, line 2 (Example 1) and the sequence listing. In addition, the specification describes methods used to analyze the claimed nucleic acid molecules and their association “involved in floral development, reproduction female reproduction and development (ovary/ovule development, stigma development and style development), pollen production and development, seed production, glume development, lemma development, palea development, and pathogen resistance or susceptibility.” *See, e.g.*, specification at page 33, lines 4-14, in the Examples at page 84, *et seq.* and in the Sequence Listing. One of ordinary skill in the art would recognize that the claimed nucleic acid molecules have utility, for example, to identify polymorphisms and markers and isolate promoters in rice

plants upon reading the present specification. These utilities are immediately apparent for the claimed nucleic acid molecules without further research.

The Examiner states that the credibility of the presently asserted utilities has not been assessed. Office Action at page 4. Credibility is precisely the issue that the courts have emphasized in evaluating the adequacy of an asserted utility. Utility is determined “by reference to, and a factual analysis of, the disclosure of the application.” *In re Ziegler*, 992 F.2d 1197, 1201, 26 U.S.P.Q.2d 1600, 1603 (Fed. Cir. 1993), *quoting Cross v. Iizuka*, 753 F.2d 1040, 1044, 224 U.S.P.Q. 739, 742 (Fed. Cir. 1985). The Examiner “has the initial burden of challenging a presumptively correct assertion of utility in the disclosure.” *In re Brana*, 51 F.3d 1560, 1567, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995). The utilities asserted in the specification must be accepted as factually sound unless the Patent Office cites information that undermines the credibility of the assertion. *Id.* The Examiner “must do more than merely question operability – [he] must set forth factual reasons which would lead one skilled in the art to question the objective truth of the statement of operability.” *In re Gaubert*, 524 F.2d 1222, 1224-25, 187 U.S.P.Q. 664, 666 (C.C.P.A. 1975) (emphasis in original); MPEP § 2107.01 (“Office personnel are reminded that they must treat as true a statement of fact made by an applicant in relation to an asserted utility, unless countervailing evidence can be provided...”). Here, the Examiner has not even attempted to meet this burden. Thus, the Examiner’s admission that the credibility of the disclosed utilities is not challenged is tantamount to an admission that no proper rejection has been made.

In view of the above, Applicants contend that the claimed nucleic acid molecules are supported by credible, specific, and substantial utilities disclosed in the specification. Moreover, the Examiner has failed to raise any credible evidence challenging the presently asserted utilities.

An invention need only provide one identifiable benefit to satisfy 35 U.S.C. § 101. Because Applicants need only establish a single utility to satisfy 35 U.S.C. § 101, and have done so in the present case, the rejection under 35 U.S.C. § 101 is improper. Reconsideration and withdrawal of this rejection are respectfully requested.

4. Claim Rejections – 35 U.S.C. § 112, Second Paragraph

Claims 1 and 2 have been rejected under 35 U.S.C. § 112, second paragraph as allegedly “being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.” Office Action at page 4.

Claims 1 and 2 are allegedly indefinite in the recitation of “substantially” because it is allegedly not clear “[w]hen ... a nucleic acid molecule [is] considered purified, as opposed to ‘substantially’ purified.” Office Action at page 5. Applicants respectfully disagree. Applicants respectfully point out that the claims are to be read in light of the specification. *See in re Vogel*, 422 F.2d 438, 441, 164 U.S.P.Q. 619, 622 (C.C.P.A. 1970). The test for determining whether terms in a given claim are indefinite is whether one skilled in the art would understand what is claimed. *Amgen, Inc. v. Chugai Pharmaceutical Co., Ltd.*, 927 F.2d 1200, 18 U.S.P.Q.2d 1016 (Fed. Cir. 1991), *cert denied*, 112 S.Ct. 169 (1991). A person of ordinary skill in the art would understand the metes and bounds of the claims read in light of the disclosure of the specification.

Applicants respectfully assert that the term “substantially” is readily understandable by one of skill in the art, particularly when considered in the context of the claim as a whole and the specification. *See, e.g.*, Specification at page 16, lines 12-18. Applicants therefore respectfully request reconsideration and withdrawal of the indefiniteness rejection of claims 1 and 2 under 35 U.S.C. § 112, second paragraph.

Further, claim 1 is allegedly indefinite in the recitation of the phrase “fragment thereof” because it is allegedly not clear whether “the recitation is referring to a fragment of the plant protein, or the nucleic acid molecule.” Office Action at page 5. Applicants respectfully disagree, however, in order to facilitate prosecution, claim 1 has been amended to delete the phrase “or fragment thereof.” Applicants respectfully request that the Examiner withdraw the indefiniteness rejection.

Accordingly, for at least the foregoing reasons, the rejection of claims 1-2 under 35 U.S.C. § 112, second paragraph is improper. Reconsideration and withdrawal of this rejection is respectfully requested.

5. Claim Rejections – 35 U.S.C. § 112, 1st Paragraph, Written Description

The Examiner has rejected claims 1 and 2 under 35 U.S.C. § 112, first paragraph, for allegedly lacking an adequate written description. Office Action at pages 5-7. Applicants respectfully disagree.

The Examiner, acknowledges that “[t]he nucleotide sequence consisting of SEQ ID NO: 4” is “explicitly disclosed.” Office Action at page 6. However, the Examiner argues that the claims “encompass full-length genes and cDNAs that are not further described.” *Id.* The basis for the Examiner’s rejection apparently is because the subject matter is “claimed with open language (comprising), the genus encompasses a variety of subgenera with widely varying attributes.” *Id.* The Examiner concludes that:

Weighing all factors, 1) partial structure of the DNAs that comprise SEQ ID NO: 4, 2) the breadth of the claims as reading on genes yet to be discovered in addition to numerous fusion constructs and cDNAs, 3) he [sic] lack of correlation between the structure and function of the genes and/or fusion constructs; in

view of the level of knowledge and skill in the art, one skilled in the art would not recognize from the disclosure that Applicants were in possession of the genus of substantially purified nucleic acid molecules which comprise SEQ ID NO: 4.

Applicants respectfully disagree.

It is well-established law that use of the transitional term “comprising” leaves the claims “open for the inclusion of unspecified ingredients even in major amounts.” *Ex parte Davis*, 80 U.S.P.Q. 448, 450 (B.P.A.I. 1948). *Accord PPG Indus. v. Guardian Indus.*, 156 F.3d 1351, 1354, 48 U.S.P.Q.2d 1351, 1353-54 (Fed. Cir. 1998); *Moleculon Research Corp. v. CBS*, 793 F.2d 1261, 1271, 229 U.S.P.Q. 805, 812 (Fed. Cir. 1986). The very nature of “unspecified ingredients” is that they are not specified or described. The Examiner attempts to turn the legal meaning of “comprising” on its head. The claims recite the required nucleic acid sequences and recite percent sequence identities. Applicants’ amended claims do not recite proteins and, accordingly, need not describe them. Applicants need only describe the claimed invention, and have done so in the present application.

The purpose of the written description requirement is to ensure that the inventor had possession of the claimed subject matter, *i.e.*, to ensure that the inventor actually invented what is claimed. *Gentry Gallery Inc. v. Berkline Corp.*, 134 F.3d 1473, 1479, 45 U.S.P.Q.2d 1498, 1503 (Fed. Cir. 1998); *Lockwood v. American Airlines*, 107 F.3d 1565, 1572, 41 U.S.P.Q.2d 1961, 1966 (Fed. Cir. 1997); *In re Alton*, 76 F.3d 1168, 1172, 37 U.S.P.Q.2d 1578, 1581 (Fed. Cir. 1996). If a person of ordinary skill in the art would, after reading the specification, understand that the inventor had possession of the claimed invention, even if not every nuance, then the written description has been met. *In re Alton*, 76 F.3d at 1175, 37 U.S.P.Q.2d at 1584. A person of ordinary skill in the art would, after reading the present specification, understand

that Applicants had possession of nucleic acid molecules comprising SEQ ID NO: 4, and therefore, the claimed invention.

For example, the specification describes gene sequences, corresponding sequences from other species, mutated sequences, SNPs, polymorphic sequences, promoter sequences, exogenous sequences, and so forth (*see, e.g.*, specification at page 25, line 10 through page 26, line 20; page 35, line 26 through page 38, line 10 and page 38, line 11 through page 45, line 21). The specification also describes appropriate hybridization conditions (*see, e.g.*, specification at 17, line 11 through page 18, line 20); nucleic acid molecules comprising nucleic acid sequences having conservative variations or encoding amino acid sequences having conservative substitutions (*see, e.g.*, specification at page 21, line 6 through page 24, line 20); fusion protein or peptide molecules or fragments thereof encoded by the nucleic acid molecules of the present invention (*see, e.g.*, specification at page 28, line 23 through 29, line 19); plant homologue proteins (*see, e.g.*, specification at page 19, line 19 through page 21, line 5); site directed mutagenesis of the claimed nucleic acid molecules (*see, e.g.*, specification at page 55, line 14 through page 56, line 27); and vectors comprising the claimed nucleic acid molecules and methods of transforming plants (*see, e.g.*, specification 61, line 3 through page 76, line 8). Despite the numerous variations described for the claimed nucleic acid molecules in the present specification, the Examiner argues that “the disclosed structural feature does not ‘constitute a substantial portion’ of the claimed genus.” Office Action at page 7.

The Federal Circuit has elucidated a test for written description wherein a genus of nucleic acids may be described by a structural feature that distinguishes members of the claimed genus from non-members of the claimed genus. *Regents of the University of California v. Eli*

Lilly and Co., 119 F.3d 1559, 1568-69, 43 U.S.P.Q.2d 1398, 1406 (Fed. Cir. 1997). Applicants have satisfied that test for written description. For example, Applicants have disclosed common structural features, for example the nucleotide sequence of SEQ ID NO: 4, and complements and variants thereof. The respective common structural feature (*e.g.*, the nucleotide sequences of SEQ ID NO: 4 and their complements) is shared by every nucleic acid molecule in the claimed genus, and it distinguishes the members of the claimed genus from non-members.

In light of the detailed disclosure of the present application, one skilled in the art, after reading the present specification, would clearly know if a nucleic acid molecule contains one of the recited nucleotide sequences. Thus, pending claims 1-2 are supported by an adequate written description pursuant to the requirements of 35 U.S.C. § 112, and the rejection should be reversed. Reconsideration and withdrawal are respectfully requested.

6. Claim Rejections – 35 U.S.C. § 112, first paragraph, enablement

Claims 1-2 were rejected under 35 U.S.C. § 112, first paragraph, as not being enabled by the specification, because the claimed invention allegedly lacks utility (*i.e.*, an invention with no utility cannot be enabled). Applicants respectfully traverse this rejection, and note that this rejection has been overcome by the foregoing arguments regarding utility.

The Examiner further alleges that “[t]he nucleotide sequence of SEQ ID NO: 4 is not predictive of the remaining sequences of the complete cDNA. As the function of the claimed nucleic acid molecule, or the protein it encodes, is not taught, one skilled in the art therefore would not know how to use it.” Office Action at page 8. The Examiner further argues that “[u]ndue experimentation would be required by one skilled in the art to determine the remaining

nucleotide sequences of the coding region that SEQ ID NO: 4 is a part of, and characterize the function of the encoded product.” *Id.* Applicants respectfully disagree.

It is well established patent jurisprudence that Applicant needs not teach “conventional and well-known genetic engineering techniques” (*see, e.g., Ajinomoto Co. v. Archer-Daniels-Midland Co.*, 228 F.3d 1338, 1345, 56 U.S.P.Q.2d 1332, 1337 (Fed. Cir. 2000)), which would include the use of the claimed sequence with other nucleic acid sequences, Applicants submit the Examiner has not met the required burden. Furthermore, Applicants submit that an analysis of the criteria presented by *In re Wands* supports Applicant’s position that no undue experimentation would be required to make and use the claimed invention. *See In re Wands*, 858 F.2d 731, 737, 8 U.S.P.Q.2d 1400, 1404 (Fed. Cir. 1998).

The first *Wands* criterion is the quantity of experimentation necessary. The “make-and-test” quantum of experimentation is reduced by the extensive knowledge, *e.g.*, of conservative nucleotide substitutions, identification of an active site, and radiometric synthase assay conditions, to which a person of ordinary skill in the art has access. Performing routine and well-known steps, such as sequence alignment protocols, molecular weight determination, and antibody hybridization assays, cannot create undue experimentation even if it is laborious. *See In re Angstadt*, 537 F.2d 498, 504, 190 U.S.P.Q. 214, 218-219 (C.C.P.A. 1976).

The second and third *Wands* criteria relate to the amount of direction or guidance given, and the presence or absence of working examples. Again, the specification provides, for example, percent sequence identity, and discusses the use of the claimed SEQ ID NO to isolate additional sequences within a genome. *See, e.g.*, specification at page 18, line 25 through page 19, line 18, page 34, line 23 through page 37, line 16, page 84, line 14 through page 90, line 3

(Examples 1-3) and the sequence listing. Based on such disclosure, one of ordinary skill in the art would be enabled to make and use the invention commensurate in scope with the claims.

The fourth, fifth and sixth *Wands* criteria focuses on the nature of the invention, the state of the art and the relative skill in the art. The present invention relates to nucleic acid sequences, and the specification further describes amino acid sequences derived therefrom, antibodies, constructs and methods related thereto. *See, e.g.*, specification at page 28, line 5 through page 29, line 19 (describing polypeptide molecules and homologues), page 68, line 7 through page 76, line 23 (describing use of the claimed nucleic acid molecules in methods of transforming plants), and page 80, lines 4-12 (describing resources for the construction, manipulation and isolation of macromolecules). Practitioners in this art are guided by considerable knowledge and resources on the conditions and approaches that can be utilized to identify, confirm and introduce into other hosts, nucleic acid and amino acid sequences.

The seventh criterion considers the predictability of the art. The Examiner has presented no evidence why one of ordinary skill in the art would not, for example, be able to predict conservative substitutions or use the nucleic acid molecules of the present invention in the disclosed uses. Applicant asserts that the specification discloses sufficient guidance to render these results predictable. *See, e.g.*, Specification at page 21, line 6 through page 24, line 20, and page 81, line 19 through page 84, line 12.

The eighth criterion focuses on the breadth of the claims. Enablement is satisfied when the disclosure “adequately guide[s] the art worker to determine, without undue experimentation, which species among all those encompassed by the claimed genus possess the disclosed utility”. *See In re Vaeck*, 947 F.2d 488, 496, 20 U.S.P.Q.2d 1438, 1445 (Fed. Cir. 1991). In the present

case, one of skill in the art is specifically guided by the disclosure to look to, *e.g.*, sequence identity data in making that determination.

The Examiner has provided neither evidence supporting the rejection nor any explanation of why the specification allegedly fails to enable the nucleic acid molecules of claims 1 and 2. *See In re Wright*, 999 F.2d 1557, 1561-62, 27 U.S.P.Q.2d 1510, 1513 (Fed. Cir. 1993); *Ex parte Lemak*, 210 U.S.P.Q. 306, 307 (B.P.A.I. 1981) (“pure conjecture” does not substantiate rejection for lack of enablement). Moreover, because the above analysis illustrates that the specification clearly enables at least the methods of making and using the invention as set forth in the Examples, and the claims, the enablement requirement has been satisfied. *Cf. Johns Hopkins University v. CellPro*, 152 F.3d 1342, 1361, 47 U.S.P.Q.2d 1705, 1719 (Fed. Cir. 1998) (“the enablement requirement is met if the description enables any mode of making and using the invention”) (emphasis added), *quoting Engel Indus. v. Lockformer Co.*, 946 F.2d 1528, 1533, 20 U.S.P.Q.2d 1300, 1304 (Fed. Cir. 1991). Furthermore, the analysis of the *Wands* factors, discussed *supra*, conclusively establishes that one of ordinary skill in the art would be able to make and use the claimed invention based on the disclosure in the specification. Accordingly, Applicants respectfully request reconsideration and withdrawal of the enablement rejection under 35 U.S.C. § 112, first paragraph.

Conclusion

In view of the foregoing remarks, Applicants respectfully submit that the present application is now in condition for allowance, and notice of such is respectfully requested. The Examiner is encouraged to contact the undersigned at (202) 942-5085 should any additional information be necessary for allowance.

Respectfully submitted,

Handwritten signatures of Thomas E. Holsten and David R. Marsh, written in black ink over a horizontal line.

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